#### NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

ORTHO-McNEIL PHARMACEUTICAL, :

INC., : CIVIL ACTION NO. 04-1689 (SRC)

:

Plaintiff, :

MEMORANDUM OPINION

v.

MYLAN LABORATORIES, INC., et al.,

:

Defendants.

:

### CHESLER, District Judge

This matter comes before the Court on the motion by defendants, Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc. (collectively "Mylan"), for summary judgment of noninfringement of U.S. Patent No. 4,513,006 ("the '006 patent") held by plaintiff Ortho-McNeil Pharmaceutical, Inc. ("Ortho"), pursuant to Federal Rule of Civil Procedure ("Rule") 56. The Court, for the reasons stated herein, will deny Mylan's motion.

#### BACKGROUND

# I. <u>Procedural History</u>

Dr. Bruce Maryanoff, a scientist at Ortho's predecessor

McNeil Laboratories ("McNeil"), discovered a chemical compound

known as topiramate in 1978. (Pl. Rule 56.1 Statement ("Pl.

Facts") at ¶ 45; Def. Resp. Rule 56.1 Statement ("Def. Facts

Resp. ") at ¶ 45.) Maryanoff directed topiramate be submitted

for evaluation in various vivo pharmacological assays at McNeil,

including evaluation for use as an anticonvulsant. (P1. Facts at ¶ 47; Def. Facts Resp. at ¶ 47.) McNeil initiated pre-clinical trials of topiramate in late 1983. (P1. Facts at ¶ 53; Def. Facts Resp. at ¶ 53.) Maryanoff and his co-inventor filed a patent application based on their work in September 1983. (P1. Facts at ¶ 49; Def. Facts Resp. at ¶ 49.) The '006 patent, entitled ANTICONVULSANT SULFAMATE DERIVATIVES, was issued on April 23, 1985. (P1. Facts at ¶ 49; Def. Facts Resp. at ¶ 49; Compl. at ¶ 10.) The '006 patent was assigned to McNeil. (Compl. at ¶ 50; Def. Facts Resp. at ¶ 50.) Ortho, as a corporate successor of McNeil, currently owns the '006 patent. (P1. Facts at ¶ 50.) Ortho applied to have the patent extended five years beyond its expected termination from September 2003 to September 2008 and that application was granted on March 11, 2003. (Compl. at ¶ 13.)

The Food and Drug Administration ("FDA") approved topiramate for the treatment of epilepsy in December 1996. (Pl. Facts at ¶ 55; Def. Facts Resp. at ¶ 55.) Ortho markets topiramate products under the trade name TOPAMAX. (Pl. Facts at 56; Def. Facts Resp. at 56.) TOPAMAX is currently approved by the FDA for the treatment of seizures. (Def. Facts Resp. at ¶ 55.) The FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book," lists the '006 patent as covering topiramate. (Pl. Facts at ¶ 57; Def. Facts Resp. at ¶ 57.)

Mylan filed an Abbreviated New Drug Application ("ANDA") with the FDA for topiramate on December 26, 2001. (Pl. Facts at ¶ 40; Def. Statement Facts at ¶ 40.) The FDA tentatively approved Mylan's ANDA on April 23, 2003. (Pl. Facts at ¶ 41; Def. Statement Facts at ¶ 41.) Mylan sent Ortho written notice of its ANDA on March 2, 2004. (Compl. at ¶ 16.) That notice certified that the '006 patent was invalid and therefore "'[n]o valid claim of the '006 patent will be infringed by the manufacture, use, sale or offer for sale' of Mylan's topiramate tablets." (Def. Statement Facts at ¶ 41; Compl. at ¶ 16.) Mylan also noticed Ortho that it sought FDA approval to market the product claimed in the ANDA prior to the expiration of the '006 patent. (Compl. at ¶ 16.)

Ortho filed suit against Mylan on April 12, 2004 claiming willful infringement and infringement of the '006 patent.

(Compl. at ¶¶ 17-22.) Mylan counterclaimed on May 20, 2004, seeking, inter alia, a declaratory judgment that Ortho's '006 patent does not claim topiramate. (Ctrclm. at ¶¶ 13-17.) Mylan filed a motion to dismiss Ortho's willful infringement claim, pursuant to Rule 12(c), on August 11, 2004. Mylan then filed a motion for summary judgment of noninfringement, pursuant to Rule 56, on October 8, 2004. The Court heard oral argument on the motion to dismiss on April 18, 2005, and granted Mylan's motion on April 19, 2005.

The Court held a <u>Markman</u> hearing concerning Mylan's summary judgment motion on May 6, 2005. The Court heard from the following expert witnesses presented by Ortho: (1) Dr. Samuel J. Danishefsky, an organic chemist; (2) Dr. Craig A. Sirles, a linguist; and (3) James P. Ryther, a patent attorney. Mylan presented no expert witnesses before the Court.

The <u>Markman</u> hearing focused on a particular section of claim 1 of the '006 patent, which the parties agree is the sole disputed issue remaining in this matter. (Pl. Post-<u>Markman</u> Br. at 1; Def. Post-<u>Markman</u> Br. at 1.) The section in dispute reads, "R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub> and R<sub>5</sub> are independently hydrogen or lower alkyl and R<sub>2</sub> and R<sub>3</sub> and/or R<sub>4</sub> and R<sub>5</sub> together may be a group of the following formula (II)." (Sarah E. Reindl Decl., Ex. D, U.S. Patent No. 4,513,006 ("U.S. Patent No. 4,513,006"); Pl. Post-<u>Markman</u> Br. at 1.)

### II. The Science

Claim 1 of the '006 patent is the only independent claim in the '006 patent. (Def. Summ. J. Br. at 2.) Claim 1 referenced in the '006 patent specification, states:

A sulfamate of the following formula (I):

$$R_5$$
 $R_4$ 
 $R_3$ 
 $CH_2OSO_2NHR_1$ 
 $R_2$ 

X is oxygen; R<sub>1</sub> is hydrogen or alkyl; and

 $R_2$ ,  $R_3$ ,  $R_4$  and  $R_5$  are independently hydrogen or lower alkyl and  $R_2$  and  $R_3$  and/or  $R_4$  and  $R_5$  together may be a group of the following formula (II):

wherein

 $R_6$  and  $R_7$  are the same or different and are hydrogen, lower alkyl or are alkyl and are joined to form a cyclopentyl or cyclohexyl ring.

(U.S. Patent No. 4,513,006 Patent; Def. Statement Facts at ¶ 14; Pl. Claim Constr. Br. at 5, 9.)

The parties do not dispute that formula (II) in independent Claim 1 includes topiramate. (Pl. Facts at ¶ 70; Def. Facts Resp. at ¶ 70.) The conflict arises over whether formula (II) can be considered part of independent Claim 1, such that Claim 1 covers two alternative groupings of  $R_2$  through  $R_5$ . (Pl. Post-Markman Br. at 1; Def. Post-Markman Br. at 1.)

Under formula (I),  $R_2$  through  $R_5$  individually form single bonds with the carbon ring. (Pl. Claim Constr. Br. at 7; Markman Tr., Danishefsky Test., at 25-28.) When  $R_2$  through  $R_5$  are independent they are either hydrogen or lower alkyl. (Markman Tr., Danishefsky Test., at 34-39.) Under formula (II),  $R_2$  and  $R_3$  and/or  $R_4$  and  $R_5$  together pair at corresponding parts of the carbon ring. (Id. at 39-41.) When  $R_2$  and  $R_3$  and/or  $R_4$  and  $R_5$  are together, they are not hydrogen or lower alkyls. (Id.; see also Pl. Facts at ¶ 43; Def. Facts at ¶ 43.) Rather, when  $R_2$  and  $R_3$ 

and/or  $R_4$  and  $R_5$  are together they express groups described in formula (II) and are paired as oxygen. (Markman Tr., Danishefsky Test., at 39-41; Pl. Facts at ¶ 43; Def. Facts at ¶ 43.)

Dependent Claim 5, which both parties agree represents the chemical structure of topiramate, is referenced in the '006 patent. (Pl. Facts at ¶¶ 69-71; Def. Facts Resp. at ¶¶ 69-71; U.S. Patent No. 4,513,006.)

Mylan argues that the compound described in Claim 1 requires that R<sub>2</sub> through R<sub>5</sub> must be hydrogen or lower alkyls, and not paired as oxygen as described in formula (II). (See Def. Summ. J. Br. at 1-2, 12-13.) Mylan, thus, argues that topiramate, which requires the pairing of atoms that are not exclusively hydrogen and lower alkyls, is an impermissible extension of the '006 patent because formula (I) and formula (II) cannot exist simultaneously. (Markman Tr., Danishefsky Test., at 62:15-19; Id. at Mylan Arg., at 130; see Def. Facts at ¶ 28.) Mylan, therefore, contends that the '006 patent does not claim topiramate, rather the '006 patent specification merely discloses it. (Def. Summ. J. Br. at 13-14.)

Ortho argues that "Claim 1 expresses two alternatives for the R groups, one in which the R's are independent—they are then

Claim 5 in the '006 patent was originally designated as Claim 7 in the patent application. (Markman Tr., Ryther Test., at 109-110; Pl. Ex. 4, Patent Prosecution History ("Patent Prosecution History"), at 23.)

hydrogen or lower alkyl—and the other in which they are together—they are paired together in the structure of formula (II)." (Pl. Post—Markman Br. at 1.) Ortho contends that the use of the signal words "independently" and "together" in the disputed language of Claim 1 indicates that the word "and" expresses these alternatives. (Id. at 1-2.) Ortho also argues that if Claim 1 is read to exclude formula (II), as Mylan contends, then the dependent claims in the '006 patent and patent specification, particularly Claim 5, would have no meaning. (Id. at 2-3.) Ortho, therefore, asserts that the '006 patent expressly claims topiramate. (Id. at 10.)

### III. Patent Prosecution History

Claim 1 in Ortho's patent application initially read:
A sulfamate for the following formula (I):

$$R_5$$
 $R_4$ 
 $R_3$ 
 $CH_2OSO_2NHR_1$ 
 $R_2$ 

wherein

X is CH<sub>2</sub> or oxygen;

R<sub>1</sub> is hydrogen or alkyl; and

 $R_2$ ,  $R_3$ ,  $R_4$  and  $R_5$  are independently hydrogen or lower alkyl and, when X is  $CH_2$ ,  $R_4$  and  $R_5$  may be alkene groups joined to form a benzene ring and, when X is oxygen,  $R_2$  and  $R_3$  and/or  $R_4$  and  $R_5$  together may be a methylendioxy group of the following formula (II):

wherein

 $R_6$  and  $R_7$  are the same or different and are hydrogen, lower alkyl or are alkyl and are joined to form a cyclopentyl or cyclohexyl ring.

(Patent Prosecution History at 21; Pl. Facts at 73; Def. Facts Resp. at 73.)

Claim 7 of the application, later re-designated as Claim 5, read:

The sulfamate of claim [six, which became claim four], wherein said sulfamate is 2,3:4,5-bis-O-(1-methylethylidene)- $\beta$ -D-fructopyranose sulfamate.

(Patent Prosecution History at 23.)

The patent examiner, during the patent prosecution, struck parts of Claim 1, so it read:

A sulfamate for the following formula (I):

wherein

X is CH<sub>2</sub> or oxygen;

R<sub>1</sub> is hydrogen or alkyl; and

 $R_2$ ,  $R_3$ ,  $R_4$  and  $R_5$  are independently hydrogen or lower alkyl and, when X is  $CH_2$ ,  $R_4$  and  $R_5$  may be alkene groups joined to form a benzene ring and, when X is oxygen,  $R_2$  and  $R_3$  and/or  $R_4$  and  $R_5$  together may be a methylendioxy group of the following formula (II):

wherein

 $R_6$  and  $R_7$  are the same or different and are hydrogen, lower alkyl or are alkyl and are joined to form a cyclopentyl or cyclohexyl ring.

(Id. at 21; see also Pl. Facts at ¶ 78; Def. Facts Resp. at ¶ 78.)

The patent examiner struck the referenced language because it covered a substance other than topiramate and thus covered more subject matter than was appropriately within the scope of the patent. (Markman Tr., Ryther Test., at 117; Pl. Claim Constr. Br. at 11.) The patent examiner, however, did not strike, alter, or amend the language related to formula (II) in Claim 1, which the parties agree specifically discloses topiramate. (Patent Prosecution History at 21; Pl. Facts at ¶¶ 79-81; Def. Resp. Facts at ¶¶ 79-81; Pl. Claim Constr. Br. at 11.) Nor did the patent examiner strike, alter, or substantively amend the language of Claim 5, which both parties concede discloses topiramate. (Patent Prosecution History at 23; Pl. Claim Constr. Br. at 11.)

#### **DISCUSSION**

#### I. Relevant Law

## A. <u>Summary Judgment Standard</u>

Rule 56(c) provides that summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as

a matter of law." The party moving for summary judgment bears the initial burden of showing that there is no genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). Once the summary judgment movant has met this prima facie burden, the nonmovant "must set forth specific facts showing that there is a genuine issue for trial." Fed.R.Civ.P. 56(e). A nonmovant must present actual evidence that raises a genuine issue of material fact and may not rely on mere allegations. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986).

The Court must view the evidence in the light most favorable to the nonmovant when deciding a summary judgment motion.

Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986). At the summary judgment stage, the Court's role is "not . . . to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." Anderson, 477 U.S. at 249. Under this standard the "mere existence of a scintilla of evidence in support of the [nonmovant's] position will be insufficient [to defeat a Rule 56(c) motion]; there must be evidence on which the jury could reasonably find for the [nonmovant]." Id. at 252. "By its very terms, this standard provides that the mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact."

Id. at 247-48 (emphasis in original). A fact is material only if it might affect the action's outcome under governing law. Id. at 248. "[T]here is no issue for trial unless there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party. If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted."

Id. at 249-50 (citations omitted).

## B. Patent Infringement

There are two steps in analyzing patent infringement. The Court first construes the claim to determine its meaning and scope and then compares "the properly construed claims to the accused device." Bell Atl. Network Servs., Inc. v. Covad Commun.

Group, Inc., 262 F.3d 1258, 1267 (Fed. Cir. 2001); Innova/Pure

Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004). Claim construction is a question of law.

Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1201 (Fed. Cir. 2002). A party can infringe an independent claim without infringing a dependent claim, but the "reverse is not true." Wahpeton Canvas Co., Inc. v. Frontier, Inc., 870 F.2d 1546, 1552 n.9 (Fed. Cir. 1989). Dependent claims contain the limitations expressed in the independent claim and are narrower than the independent claim. Id. at 1553.

The Court should construe claims to sustain their validity, if possible. Rhine v. Casio, Inc., 183 F.3d 1342, 1345 (Fed. Cir. 1999); see also Vitronics Corp. v. Conceptronic, Inc., 90

F.3d 1576, 1583 (3d Cir. 1996) (noting that a claim construction that eliminates all embodiments of the invention "is rarely, if ever, correct and would require highly persuasive evidentiary support"). The Court, however, should not "redraft claims" to sustain their validity. Chef America, Inc. v. Lamb-Weston, Inc., 358 F.3d 1371, 1374 (Fed. Cir. 2004). "[I]f the only claim construction that is consistent with the claim's language and the written description renders the claim invalid, . . . the claim is simply invalid." Rhine, 183 F.3d at 1345. This is true even if the result is "nonsensical." Chef America, 358 F.3d at 1374 (citation omitted).

The Court, in construing a claim, must first consider "the claim language itself to define the scope of the patented invention." Bell Atl., 262 F.3d at 1267. The Court focuses its analysis on the plain meaning of the claim language because "it is that language that the patentee chose to use to particularly point[] out and distinctly claim the subject matter which the patentee regards as his invention." Tex. Digital, 308 F.3d at 1201-02 (citations and internal quotations omitted). There is a "heavy presumption" that the claim language has its ordinary meaning to one skilled in the art of the invention, except where the inventor has given the term a special meaning in the patent specification. Innova, 381 F.3d at 1116; Bell Atl., 262 F.3d at 1267-68. The Court should give a claim term its full range of meaning. Tex. Digital, 308 F.3d at 1202.

The Court must then consider the plain meaning of a term "in the context of all intrinsic evidence," including the claims, the patent specification, and the prosecution history. 3M Innovative Props. Co. v. Avery Dennison Corp., 350 F.3d 1365, 1371 (Fed. Cir. 2003). "Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." Bell Atl., 262 F.3d at 1267. The Court must review the specification "to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning. The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." Vitronics, 90 F.3d at 1582. The Court must examine the prosecution history to determine "whether or not there were any express representations made [by the applicant] regarding the scope of the claims." Bell Atl., 262 F.3d at 1268. The prosecution history is often crucial to define claims and their scope because it is a "complete record of all the proceedings before the Patent and Trademark Office." Id. The prosecution history, therefore, helps the Court determine if the patentee "clearly and unambiguously disclaimed or disavowed [any interpretation] during prosecution in order to obtain claim allowance." 3M, 350 F.3d at 1371 (quotations and citations omitted).

The Court, generally, may not rely on extrinsic evidence to ascertain the plain meaning of a term. <u>Bell Atl.</u>, 262 F.3d at 1269-70. Such evidence, however, may be considered when it is

necessary to resolve persisting ambiguities not resolved by consideration of intrinsic evidence alone. <u>Vitronics</u>, 90 F.3d at 1584. Extrinsic evidence "may not be used to vary, contradict, expand, or limit the claim language from how it is defined, even by implication, in the specification or file history." <u>Bell Atl.</u>, 262 F.3d at 1269. Extrinsic evidence is evidence that is "external to the patent and file history, such as expert testimony, inventor testimony, dictionaries, and technical treatises and articles." Vitronics, 90 F.3d at 1584.

Although a dictionary is extrinsic evidence, it is a special kind of extrinsic evidence. See id. The Court may properly use a dictionary to construe a claim term, "so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." Id. at 1584 n.6.

Because words often have multiple dictionary definitions, some having no relation to the claimed invention, the intrinsic record must always be consulted to identify which of the different possible dictionary meanings of the claim terms in issue is most consistent with the use of the words by the inventor. If more than one dictionary definition is consistent with the use of the words in the intrinsic record, the claim terms may be construed to encompass all such consistent meanings. The objective and contemporaneous record provided by the intrinsic evidence is the most reliable guide to help the court determine which of the possible meanings of the terms in question was intended by the inventor to particularly point out and distinctly claim the invention.

Tex. Digital, 308 F.3d at 1203 (citations omitted); see also
Renishaw PLC v. Marposs Societa' Per Azioni, 158 F.3d 1243, 1250

(Fed. Cir. 1998) ("[W]here there are several common meanings for a claim term, the patent disclosure serves to point away from the improper meaning and toward the proper meaning.").

The Federal Circuit applied the plain meaning construction rule when finding non-infringement of a dough product in <a href="Chef">Chef</a>
<a href="America">America</a>. 358 F.3d at 1374-76. The appeal in <a href="Chef">Chef America</a>
<a href="Centered">Centered</a> on the following language in the patent claim: "heating the resulting batter-coated dough to a temperature in the range of about 400 degrees F. to 850 degrees F." <a href="Id">Id</a>. at 1371. The debate centered on whether the claim referred to the temperature of the oven or the dough. <a href="Id">Id</a>. at 1371-72. The Federal Circuit refused to read "to" to mean "at" since "[n]othing even remotely suggested that what is to be heated is not the dough but the air inside the oven in which the heating takes place." <a href="Id">Id</a>. at 1373. In so holding the Federal Circuit stated that the meaning of the ordinary, simple words "is clear and unquestionable. There is no indication that their use in this particular conjunction changes their meaning. They mean exactly what they say." <a href="Id">Id</a>.

The Federal Circuit in Renishaw held that the context in which a term appears can dictate its meaning. 158 F.3d at 1250. The issue in Renishaw concerned the definition of "when" in a claim. Id. at 1250-51. The Federal Circuit found that the district court properly defined "when" by referring to the entire claim limitation. Id. at 1250. The Renishaw court stated:

The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction . . . A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent.

Id. The court recognized that "when" had "several closely-related, but distinct, common meanings" according to the dictionary and based on its context. Id. at 1251. The court noted: "As evidenced by the several common meanings of 'when,' the term is imprecise as used in [the patent]." Id. The court, however, held that the term was not ambiguous because the written description in the patent specification provided "overwhelming evidence to guide a proper interpretation of the term." Id.

#### II. Analysis

Ortho claims that Mylan's filing of an ANDA, seeking approval to manufacture, use, and offer for sale topiramate tablets prior to the expiration of Ortho's '006 patent, constitutes patent infringement. (Compl.) Mylan claims that it is not infringing Ortho's '006 patent because it does not properly claim topiramate. (Ctrclm.) The Court finds that the plain language of Claim 1 and the patent prosecution history demonstrate that Claim 1 of the '006 patent may be properly construed to claim topiramate.<sup>2</sup>

The Court need not consider the second step in our analysis of patent infringement, comparing the properly construed claims to the accused device. <u>See Bell Atl.</u>, 262 F.3d at 1267. Both Ortho and Mylan agree that the central issue in this matter

The parties dispute the meaning of "and" in Claim 1. The word "and" has multiple dictionary definitions. Webster's Third New International Dictionary defines "and" to mean, inter alia: "along with or together with" or "as a function word to express... reference to either or both of two alternatives." WEBSTER'S 3d NEW INTERNATIONAL DICTIONARY at 80 (Merriam-Webster 1993) ("Webster's"). Mylan contends that "and" as used in the '006 patent means "along with or together with" and can only be used in the conjunctive sense. (Def. Post-Markman Br. at 6-7.)3
Ortho contends that "and" is properly being used in the '006 patent to express alternatives. (Pl. Post-Markman Br. at 4-5; Pl. Claim Constr. Br. at 13-14.) The Court agrees with Ortho.4

is the construction of Claim 1. ( $\underline{\text{See}}$  Pl. Post- $\underline{\text{Markman}}$  Br. at 1; Def. Post-Markman Br. at 1.)

Mylan relies on <u>Patient Transfer Sys., Inc. v. Patient Handling Solutions, Inc.</u>, No. 97-1568, 2000 WL 726792, at \*3 (E.D. Pa. June 6, 2000), for the proposition that "and" should be understood only in its conjunctive sense. (Def. Post-<u>Markman</u> Br. at 8.) The court in <u>Patient Transfer</u> held that "and" should have a consistent meaning throughout the patent. <u>Patient Transfer</u>, 2000 WL 726792, at \*3-\*4. The controversy in <u>Patient Transfer</u>, however, was whether "and" could be read as "and/or," which was not listed in <u>Webster's</u> as a definition for "and." <u>Id.</u> at \*3. Limiting "and" to a single meaning here would conflict with the principle that a word should have its full range of dictionary meanings that are proper within the context. <u>See Tex. Digital</u>, 308 F.3d at 1202-03.

This case is distinguishable from <u>TFH Publ'ns, Inc. v.</u>

<u>Hartz Mountain Corp.</u>, No. 02-1460, slip op. at 2 (Fed. Cir. May 30, 2003), where the claim read "formed by the reaction of aliphatic dicarboxylic acid <u>and</u> aromatic diisocyanate." (emphasis added). The court held that since the direct reaction of these two chemicals could not form the patented product, which the "and" implied it could, the patent was invalid. <u>Id.</u> at 3-5.

Ortho used "and" to express alternatives in the '006 patent and patent specification, stating: " $R_2$ ,  $R_3$ ,  $R_4$  and  $R_5$  are independently hydrogen or lower alkyl and  $R_2$  and  $R_3$  and/or  $R_4$  and  $R_5$  together may be a group of the following formula (II)." U.S. Patent No. 4,513,006 (emphasis added). Claim 1 describes  $R_2$  through  $R_5$  when they are in two different conditions. In one condition,  $R_2$  through  $R_5$  are independent of each other and either hydrogen or lower alkyl. In the second condition,  $R_2$  and  $R_3$  are paired together and/or  $R_4$  and  $R_5$  are paired together, creating topiramate, as expressed in formula (II). Claim 1 signals the use of "and" to express alternatives by using the word "independently" to describe one set of circumstances and the word "together" to describe another.

Nothing in this construction requires that  $R_2$  through  $R_5$  must always be hydrogen or lower alkyls as Mylan contends. Instead,  $R_2$  through  $R_5$  must be hydrogen or lower alkyls when they are independent of each other. When  $R_2$  and  $R_3$  and/or  $R_4$  and  $R_5$  are together, they are permitted to be of the group described in formula (II). This case, unlike <u>Chef America</u>, does not revolve around one word changing the meaning of the entire claim. Here, Ortho's use of "and" in Claim 1 might not be the most common use

There was no other way to read the disputed language in <u>TFH</u>, whereas here, in the context of the claim, "and" is consistent with a dictionary definition, in that "and" can reasonably express alternatives.

of the word, but it is a permissible use of the word as defined by <u>Webster's</u>. The Court, accordingly, finds that the plain language of Claim 1 expresses alternative chemical structures such that topiramate is expressly claimed by the '006 patent.

The prosecution history also demonstrates that topiramate is claimed by the '006 patent. During the patent prosecution history, the patent examiner struck a portion of independent Claim 1, and the dependent claims stemming from it. See supra Background, III. The examiner, however, did not strike the disputed language in Claims 1 and 5, the language that specifically claims topiramate. See id. The prosecution history, thus, demonstrates that the patent examiner considered both formulas (I) and (II) to be part of the same claim. Instead of disavowing any claim to formula (II) and topiramate, the patent prosecution history was clearly directed to topiramate. This interpretation of the prosecution history is consistent with the context of the '006 patent, as well as the plain language the '006 patent and the patent specification. The Court,

The parties have argued over whether the claim would be permissible if "or" were used in place of "and." (See Pl. Post-Markman Br. at 7-8; Def. Post-Markman Br. at 5-6.) Such an argument is irrelevant since the patentee is bound by the words in the patent. See Nellcor Puritan Bennett, Inc. v. Masimo Corp., 402 F.3d 1364, 1369 (Fed. Cir. 2005) ("While it may be that, in hindsight, the patentees would have been wise to choose a word other than 'filtered,' it is clear that they meant for that term to describe the 'relative reduction' process set forth in the specification.").

<sup>&</sup>lt;sup>6</sup> See Renish<u>aw</u>, 158 F.3d at 1250.

accordingly, finds that the prosecution history demonstrates that Claim 1 of the '006 patent may be properly construed to claim topiramate.

### CONCLUSION

The Court, for the reasons stated <u>supra</u>, holds that the plain language of Claim 1 of the '006 patent and the patent specification, as well as the patent prosecution history, may be properly construed to expressly claim topiramate. The Court, therefore, will deny Mylan's motion for summary judgment of noninfringement. An appropriate order will be issued.

Dated: July 18, 2005

s/ Stanley R. Chesler
STANLEY R. CHESLER
United States District Judge